FDA Workshop on Plasma Standards – Current Practices in Freezing and Storage

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August 31, 2004

America's Blood Centers (ABC)

- A national network of locally controlled, non-profit community blood centers that provide half of the U.S. blood supply from volunteer donors.
- 76 members operate in 45 states and the Province of Québec, Canada.
- ABC's total blood collections exceeded 7.6 million donations in 2003.
- Every year, ABC members ship over 1 million liters of plasma from volunteer donors for manufacture into plasma therapeutics.

BACKGROUND

In response to an FDA Proposed Rule revising labeling and storage requirements for blood and blood components:

ABC submitted a letter on Oct. 14, 2003, stating that:

- The proposed change to storage temperatures for fresh frozen plasma (FFP) and cryoprecipitated AHF (cryo) would have a negative impact on many ABC member blood centers.
- The negative impact would be borne despite an absence of any known complaints regarding the efficacy of these products.

ABC has surveyed its members on current practices to gather more data in support of those comments.

Surveyed Blood Centers and Their Hospital Customers

About current practices for the production and storage of FFP, plasma frozen (PF), cryoprecipitate (cryo) and recovered plasma (RP)

Blood centers were asked:

- To identify which plasma products they produce and/or store an
- To describe the time frames, equipment, and temperatures at which they freeze and store those products

Hospitals were asked:

- What products they have on hand and their storage temperature

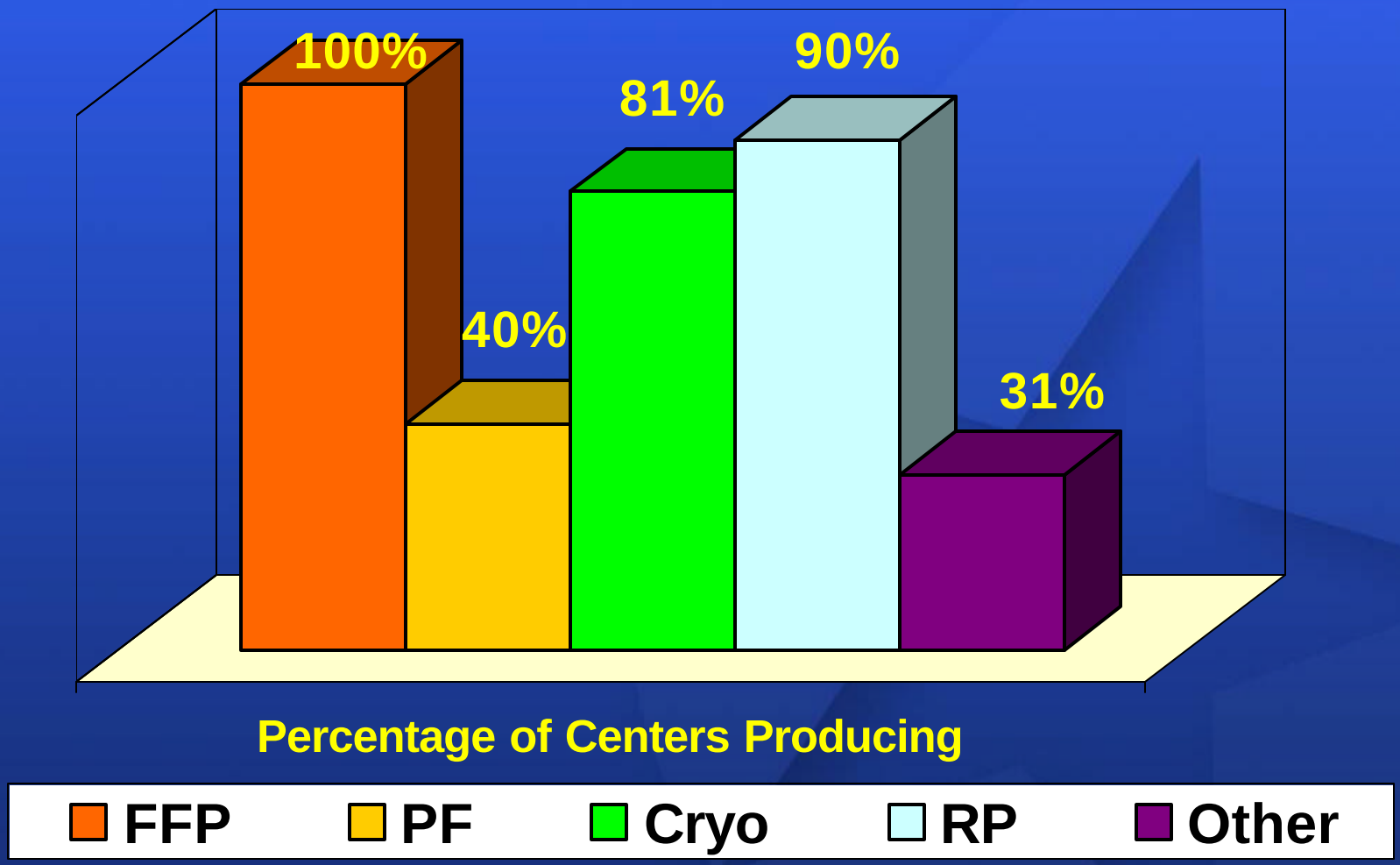
Both were asked:

- Whether they would need to modify current temperature setting or purchase new freezer(s) if the rule becomes effective
- To estimate the cost of such changes

Responses

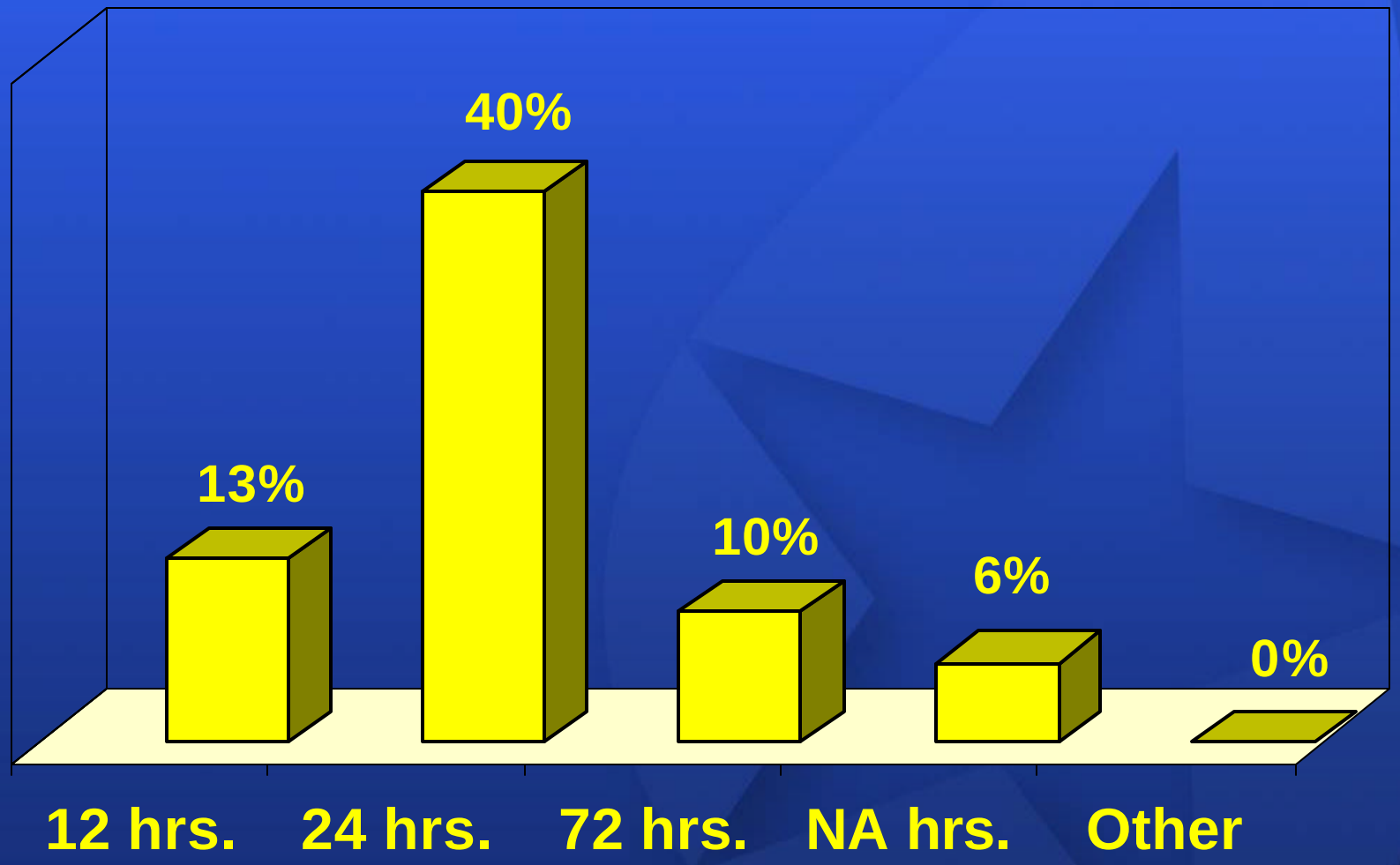
- 52 blood centers
  - 68% of ABC's membership and
  - 75% of ABC supply of 5.7 million units of WB
- 168 hospitals and other medical facilities
  - Of approximately 3,300 facilities that obtain blood from ABC members

Results – Blood Centers
Blood Products Manufactured



Results – Blood Centers

Placed in freezer (X) hours after Collection



Results – Storage Practices

	- 18 °C	- 25 °C	- 80 °C	Other
Blood Centers	52% (27)	54% (28)	0	40% (21) (Blast freezers at -50)
Hospitals (as reported by blood centers)	67% (35)	19% (10)		
Hospitals (Direct Survey)	22% (37)	68% (113)	7% (11)	8% (14)

$ Impact of Alarm Resetting

	Blood Centers	Hospitals
Yes by Manufacturer	69% (36)	41% (69)
NO	27% (14)	48% (81)
Not Sure	4% (2)	11% (18)
Cost	25% (13) Responded $500 to $1,000 Avg - $16,744	6% (17) Responded $200 to $5,000 Avg - $1,087

$ Impact of Freezer Purchase

	Blood Centers	Hospitals
Yes	40% (21)	19% (32)
NO	40% (21)	67% (114)
Not Sure	20% (10)	14% (23)
Cost	41% (20) Responded $2,000 to 280,000 Avg - $75,571	25% (41) Responded $3,000 to $30,000 Avg - $8,803

Impact – Reduced Shelf Life

- Centers and Hospitals were asked if they would accept a three-month shelf life in order to maintain storage of FFP at -18 to -20 C:
- Centers
  - 86% (44) said they would rather replace refrigeration equipment then reduce the shelf life.
- Hospitals
  - 75% (119) answered no
  - 13% (21) answered yes
  - 11% (18) were not sure
  - 6% (10) skipped the question

Surveys Summary
Blood Centers

- About half store plasma products in freezers capable of -18 ^{o}C
- Half store in freezers capable of -25 ^{o}C
- Most respondents freeze RP between -20 ^{o}C and -24 ^{o}C
- 69% said that if the FDA requires storage of FFP at -25 ^{o}C or below, maintenance contractor would have to change freezer alarm settings
- 27% (14) said no resetting necessary
- Cost estimates for resetting alarms: $500 – $100,000, with an average of $16,744
- 40% would have to purchase new freezer equipment; 40% would not; about 20% not sure.
- Cost estimates for new equipment: $2,000 – $280,000, with an average of $75,571

Surveys Summary Hospitals

- Of 168 respondents, 68% store FFP, PF, and cryo in -25 ^{o}C-capable equipment
- 41% would need to change alarm settings if rule became effective; 48% would not have to change alarm settings
- Cost estimates for alarm resetting: $200 – $5,000, with an average of $1,067
- 67% would not need new freezer equipment if FDA proposal took effect; 19% would need new equipment; 14% unsure.
- Of 41 respondents who estimated cost of new equipment, the average was $8,803, with a range of $3,000 – $30,000.

Conclusion

- ABC believes results of this extensive survey support our previous comments to FDA regarding its Proposed Rule:
  - The proposed changes are not the “Current Practice”
  - Implementation of the proposed changes DOES create an economic impact for both blood centers and hospitals
  - There needs to be a clear reason for changing the “current practices”
    - What’s wrong with product's manufactured and stored under “current” conditions?
    - How will the proposed changes IMPROVE product safety and efficacy?

Acknowledgements

- I want to thank the ABC members and hospitals that responded and
- Jane Starkey, Robert Kapler, and Karen Edwards for their help in preparing, distributing, collating and analyzing the surveys

America's Blood Centers

Thank you!

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